

REMARKS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, and 110 are pending, with claim 94 being the only withdrawn claim. By this amendment no claims have been amended, but the claims have been placed in clean form. No new matter has been introduced.

The election of species remains: (1) durum wheat as the plasticized matrix material, (2) a probiotic nutraceutical component as an encapsulant, (3) starch as the additional matrix material, and (4) liquid encapsulant as the encapsulant form. The claims readable on the elected species are Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110.

Applicant thanks the Examiner for withdrawing the previous rejection under 35 U.S.C. 112, second paragraph as being indefinite regarding use of the term "substantially" in the claims. Applicant also thanks the Examiner for withdrawing the previous rejections under 35 U.S.C. 103, involving the use of Lay et al as a secondary reference. Applicant notes the Examiner has made new grounds of rejection under 35 U.S.C. 103 involving newly cited Eden et al as a secondary reference, but has made the rejection Final alleging that the new rejections were occasioned by applicant's amendments to the claims.

THE REJECTION UNDER 35 USC 112, FIRST PARAGRAPH

Claims 31, 59, 108 and 109 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner alleges that the terms "polyvinyl acetate and derivatives thereof" and "modified starches" are unclear since Applicant's specification does not define at what point does modifying the core compound lead to a different compound that would not be considered a derivative or a modified starch

encompassed by the instant invention. This rejection is traversed for reasons as presented in the Amendment Under 37 CFR 1.111 filed on August 18, 2010, which reasons are incorporated herein in their entirety, and for reasons as presented below.

The plain, ordinary, dictionary meaning of “derivative” (Webster’s New Collegiate Dictionary G& C Merriam Co., Publishers, Springfield, MA page. 223, 1956) defines a derivative in chemistry as “A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice; thus, the amino compounds are derivatives of ammonia.” (A copy of the definition is attached.) It is well established that ordinary dictionary meanings may be used to interpret claim terms. One of ordinary skill in the art would know structures of polyvinyl acetate derivatives which are recognizable or regarded as derived from polyvinyl acetate, and would have understood the inventor to be in possession of the claimed invention at the time of filing. Also, as shown in the August 18, 2010 Amendment, modified starches are starches which have been chemically modified or incipiently hydrolyzed either by the action of added reagents or by cooking or special heat treatments, but which still give a blue or violet reaction with iodine. Furthermore, both of the terms are employed in the context of examples of hydrophobic agents which may used to control the rate of release of encapsulants. See page 13 lines 3-16. Applicant need not provide examples of examples to satisfy the written description requirement.

Applicant submits that one ordinarily skilled in the art would readily understand how to make and use the claimed encapsulated products using the claimed polyvinyl acetate derivatives and modified starches, even without express disclosure of any species of polyvinyl acetate derivatives and modified starches in Applicants’ disclosure because, *inter alia*, specific examples are known to those skilled in the art and applicant discloses and claims their function.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTIONS UNDER 35 USC 112, SECOND PARAGRAPH

Claims 31, 59, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed for reasons as presented in the Amendment Under 37 CFR 1.111 filed on August 18, 2010, which reasons are incorporated herein in their entirety, and for reasons as presented below.

The rejection of claims 31, 59, 108, and 109 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of use of the terms “derivative” and “modified starch” is untenable for reasons as given above with respect to the rejection under the first paragraph of 35 U.S.C. 112.

The Examiner maintains that it is unclear how far one can deviate from the parent compound without the derivative being so far removed therefrom so as to be a completely different compound. As discussed above, the plain, ordinary, dictionary meaning of “derivative” (Webster’s New Collegiate Dictionary G& C Merriam Co., Publishers, Springfield, MA page. 223, 1956) defines a derivative in chemistry as “A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice; thus, the amino compounds are derivatives of ammonia.” (A copy of the definition is attached.) It is well established that ordinary dictionary meanings may be used to interpret claim terms. One of ordinary skill in the art would have understood a structure related to the structure of polyvinyl acetate. One of ordinary skill would have understood the meaning of “derivative” in the context of the term “polyvinyl acetate derivative,” and in the context of the specification and claims alone (which recite its hydrophobic agent function), or with the ordinary dictionary meaning of a “derivative”.

Also, as shown in the August 18, 2010 Amendment, modified starches are well known as starches which have been chemically modified or incipiently hydrolyzed either by

the action of added reagents or by cooking or special heat treatments, but which still give a blue or violet reaction with iodine.

Furthermore, the terms are employed in the context of examples of hydrophobic agents which may used to control the rate of release of encapsulants. See page 13 lines 3-16. Applicant need not provide examples of examples to satisfy the second paragraph of 35 U.S.C. 112. Additionally, the terms are well known as further exemplified by Newton et al (USP 4,938,967) at col. 8 lines 61-65, and col. 9 lines 18-29, and Wittwer et al (USP 4,738,724) at col. 7 line 67 to col. 8 line 24.

Reconsideration and withdrawal of the rejection is respectfully requested.

THE REJECTIONS UNDER 35 U.S.C. 103

Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of newly cited Eden et al (U.S. Patent No. 4,755,397). This rejection is respectfully traversed.

Newton et al does not teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, or particles where an encapsulant is dispersed throughout the plasticized mass of each particle, as claimed in independent claims 25, 27, 52, 54, and 83, and their dependent claims. Moreover, Newton et al teaches away from the highly crystalline, retrograded starch matrix of Eden et al which contains collapsed polymer chains, and even if the references were properly combinable, applicant's claimed products would not be obtained or rendered obvious.

The Examiner employs Newton et al as teaching pharmaceutical compositions. The Examiner admits that Newton et al does not disclose the exact amounts of matrix material or encapsulant, but concludes that the amounts claimed, such as the amount of matrix material, is a result effective variable. However, the Examiner has not presented any evidence, by

way of references or otherwise, to establish that the amount of matrix material is a result effective variable.

The Examiner maintains that Newton et al discloses that generally water is added to the compositions to aid in pelletization, encompassing a water plasticizer. However, just because a plasticizer may be present does not mean that a matrix material such as starch is plasticized. As disclosed in the present specification, a sufficient amount of water and high temperatures are needed to gelatinize starch and produce a plasticized matrix from starch. See, for example, page 7 lines 4-15, page 8 line 22 to page 9 line 5, and page 22 line 12 to page 23 line 3. Mere mixing of starch and water does not produce a plasticized mass as claimed. As demonstrated by the data shown in Table 1 and FIG. 6, in Comparative Example 2 (M1) pure starch does not present a sufficient matrix for encapsulation, because the time to release 100% of the encapsulant is too short.

Newton et al employs a weighting agent to increase density beyond normal levels to thereby increase release time. The weighting agent generally is employed in an amount of at least 50% by weight of the unit, and generally has a density of at least 2.5 g/ml. The weighting agent may be a powder such as barium sulphate, ferric oxide, ferrum redactum, titanium dioxide and aluminum oxide or hydroxide, calcium carbonate, barium phosphate, bismuth phosphate, calcium aluminosilicate, zirconium silicate, calcium phosphate, silicon carbide, and magnesium carbonate. See col. 4 lines 33-52, col. 5 lines 7-9, and col. 9 line 43 to col. 10 line 1.

Newton et al discloses the use of a conventional matrix binder which may be a synthetic polymer or natural polymer or derivative such as starch or preferably cellulose or its derivatives. A known gastric controlled release binder may also be employed such as hydrophobic acrylic polymers or cellulose derivatives, vinyl polymers and other high molecular weight natural polymer derivatives or synthetic polymers. See col. 8 line 61 to col. 9 line 36. Each unit may comprise a homogeneous or non-homogeneous blend of the active ingredient and the weighting agent and any matrix binder component. For instance

each unit may have a core of weighting agent covered by a shell of active ingredient or vice versa or it may be formed of a blend of the active ingredient and the weighting agent. See col. 10 lines 58-64. The preferred method for forming the pellets or other units is to make a mixture of the weighting agent and the active ingredient and matrix binder and then to form the mixture into the units. Generally some water is added to the mixture to aid pelletization. See col. 11 lines 34-44. Use of starch as a conventional matrix binder would result in rapid release properties, and necessitates the use of a weighting agent to increase density and increase release time in accordance with the disclosure of Newton et al.

Newton et al does not teach or suggest use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, and there is no reason to do so. Furthermore, admixing a starch with the encapsulant and the weighting agent, and heating the mixture to plasticize the starch would destroy the encapsulant. There is no teaching, suggestion, or expectation that plasticizing the starch binder of Newton et al, would have a beneficial effect on the release properties of the Newton et al composition and would not destroy the encapsulant.

The Examiner admits that Newton et al does not disclose the starch is plasticized by heating. However, Newton et al does not disclose production of a plasticized mass with or without heating. The Examiner asserts that Eden et al discloses a heated plasticized starch matrix and it would be obvious to one ordinarily skilled in the art to "to have used a heated plasticized starch matrix in the formulations of Newton et al motivated by the desire to use a composition that is temperature stabilized and provides a protective colloid to the active material, as disclosed by Eden et al." However, there is no reason to plasticize the starch of Newton et al with heating.

Eden et al discloses encapsulating a material in a starch matrix by combining the material with a high temperature-stabilized pressurized dispersion of starch in the presence of salt. The temperature-stabilized starch dispersion acts as a protective colloid; upon subsequent rapid reduction of the pressure, the mixture cools and the starch polymer chains

collapse upon themselves, encapsulating the core material in particulate form. The starch is highly crystallized and retrograded, thus forming a water insensitive product.

Retrogradation is the opposite of gelatinization. To produce the encapsulated product, the starch and material to be encapsulated are slurried in water in a saturated aqueous solution of salt, steam is injected into the slurry to disperse the starch at a pressure of at least 110 psi to raise the temperature of the slurry to 120°C to 180°C at a pressure of 55-120 psi or above, the pressure is instantly reduced to atmospheric pressure so as to reduce the temperature to 112°C or less. The precipitated-retrograded starch particles which encapsulate the added material are recovered, and the salt used in the encapsulation process may be washed from the dried starch matrix. See col. 1, lines 25-53.

However, the rapid reduction in pressure employed by Eden et al would expand the product of Eden et al, reducing its density, which is contrary to the teachings of Newton et al to employ a starch binder to increase the density of the product. Eden et al does not disclose heating of starch to plasticize it. There is no reason to heat the starch in a slurry with steam and rapidly reduce the pressure in accordance with the process of Eden et al because to do so would reduce the product density whereas Newton et al desires to increase product density and employs a weighting agent to do so.

Furthermore the process of Eden et al expands the starch polymer chains and causes them to collapse upon themselves. It is not seen how the Eden et al process plasticizes the starches without substantially destructuring or dextrinizing the starch. Eden et al does not cure the deficiencies in the disclosure of Newton et al, and even if the references were properly combinable, applicant's claimed invention would not be obtained nor rendered obvious.

The Examiner maintains that Eden et al discloses temperature ranges from 120°C to 180°C at col. 3 lines 3-8 similar to those disclosed by the applicant of up to 160°C, and therefore it is reasonable to conclude that the starches used by Eden et al are not substantially dextrinized. However, temperature is not the only factor affecting

destructurization and dextrinization. As disclosed in the present specification, high shear is directly related to high specific mechanical energy, which in turn increases the molecular destructurization and dextrinization of starch. Breakdown of the starch molecules, and in particular the amylopectin, increases the solubility of the extruded starch composition in aqueous systems. As disclosed in the present specification, high water contents, and low shear and low extruder screw speeds are employed to avoid substantial destructurization and dextrinization of starch. See pages 3, 6, 7, 9, 22, 29, 32, 33, and 36 of the present specification. Also, as discussed above, Eden et al discloses that the application of high pressure and rapid pressure release cause the starch polymer chains or molecules to collapse upon themselves. See abstract and col. 1 lines 25-54.

Eden et al desires collapse of the starch polymer chains, a high degree of crystallinity and retrogradation, and does not teach or suggest avoidance of substantial destructuring or dextrinization of starch. The references simply do not teach or suggest obtaining a plasticized matrix material while avoiding substantial destructuring or dextrinization of starch.

As to the amount of matrix material and as to the release profile recited in claims 38 and 65, the Examiner maintains that it would take no more than routine skill in the art to adjust the amount of binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65. However, Newton et al teaches that it is difficult to maintain prolonged drug availability in a chosen environment such as the stomach by choice of a binder, and that there is an urgent need to provide an entirely new mechanism by which it is possible to provide prolonged release of an active ingredient within the stomach. The mechanism employed by Newton et al is the use of a weighting agent to increase density. See col. 1 line 20 to col. 2 line 10, and col. 4 lines 33-62. Thus, contrary to the position taken by the Examiner, Newton et al teaches away from use of a binder to achieve a desired active release profile. Also, Eden et al discloses controlling release time by the amount of drying

of the product, not by the use of an ingredient such as a weighting agent. See col. 3 lines 32-41. There is no reason to modify the composition of Newton et al to change the release time as proposed by the Examiner because it is contrary to the references' teachings.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 42, 69, 70, 84, and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of newly cited Eden et al (U.S. Patent No. 4,755,397) as applied above, in further view of Jane et al (U.S. Patent No. 5,397,834. This rejection is respectfully traversed.

The Examiner admits that Newton et al. and Eden et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. The Examiner points out that Jane et al discloses biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein, that suitable starches include those derived from durum wheat, and that the reference differs from the instant claims in so far as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent.

Jane et al does not cure the deficiencies in the disclosures of Newton et al and Eden et al discussed above, and even if it were obvious to combine the teachings of Newton et al, Eden et al, and Jane et al, applicant's claimed invention would not be obtained nor rendered obvious. The Examiner maintains that Newton et al and Eden et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. As discussed above, Newton et al and Eden et al, even if properly combinable, do not teach or suggest particles where for each particle an encapsulant is dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized. Even if it were obvious to employ a starch derived from durum wheat in the product of Newton et al, which it is not, Applicant's claimed products would not be obtained nor rendered obvious.

Moreover, a starch which is derived from durum wheat is not the same as durum wheat which has different matrix forming properties and different release properties. Durum wheat contains gluten which forms a plasticizable starch-protein matrix, and as disclosed in the present invention, heating or cooking of durum wheat to gelatinize starch is not required. See, for example, page 23, lines 12-14. Use of starch derived from durum wheat would not include the gluten and would result in a different matrix and different release properties.

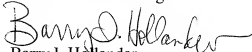
The rejection is untenable and reconsideration and withdrawal thereof is respectfully requested.

CONCLUSION

In light of the foregoing amendments and remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

It is not believed that any additional fees are due. However, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed necessary or to credit any overpayments to Deposit Account No. 19-0089 (P32853).

Respectfully submitted,
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